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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,349	12/19/2001	Yasuki Kato	5.1195	1803

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,349	KATO ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,19,20,35 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 19-20, 35 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 11-25-05 is acknowledged.

Claims included in the prosecution are 16, 19-20, 35 and 42-44.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 16, 19-20, 35 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 850,646 of record by itself or Woodle 633 cited in the previous action.

EP discloses liposome formulations containing indolocarbazole (anti-cancer agent) derivatives. The liposomes are made from hydrogenated phospholipids and PEG-DSPE (note abstract, page 4, Examples and claims). Although, EP does not explicitly state that the sizes of the liposomes, on page 4, the reference teaches various methods of preparation of liposomes, either multilamellar or unilamellar and therefore, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to prepare liposomes which are either multilamellar or unilamellar and of desired sizes

with the expectation of obtaining the best possible results. One of ordinary skill in the art would be motivated to prepare liposomes of instant sizes since the references of Woodle show the routine practice in the art of preparing liposomes of different sizes.

Applicant's arguments and the declaration have been fully considered, but are not found to be persuasive. Applicant argues that the examiner has not presented any line of reasoning as to why the artisan would have been motivated to so modify the EP-646 structure. This argument is not persuasive since as pointed out above, the reference is suggestive of both multilamellar and unilamellar liposomes and also suggestive of extrusion method so that their average particle diameter is made for e.g. to about 100 nm. Therefore, one of ordinary skill in the art would extrude the liposomes through suitable membranes to obtain liposomes having the desired diameters. The declaration and arguments based on the declaration have been fully considered, but are not found to be persuasive. First of all, the sizes claimed are 120 to 500 whereas the results presented were from liposomes of sizes 150 to 216 and therefore, the data is not commensurate with the scope of the claims. The data is also not commensurate with the scope of 'polyethylene glycol modified phospholipid' recited in the claims. Secondly, EP studies the encapsulation efficiencies of the liposomes over a period of time ranging from 0 to 24 hours and at various temperatures and determines that there is no leakage at all (see Table 3 on page 7). Furthermore, as pointed out before, applicant's conclusions are based on a single experiment. No statistical evaluation has been done of the samples.

3. Claims 16, 19-20, 35 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle 633 or 556 or Allen (4,920,016) cited in the previous action in combination with EP cited above.

As discussed in the previous action, Woodle discloses a method of preparation of multilamellar vesicles (MLVs) containing a drug. The liposome sizes are 160 nm. The drugs include both steroidal and non-steroidal anti-inflammatory agents and anticancer agents. The liposomes are made from either hydrogenated soy phosphatidylcholine or PEG-DSPE (note the abstract, Examples, Example 4 in particular and claims).

Similarly, Woodle (556) discloses liposomes containing a drug. The liposome sizes are either 160 or 170 nm. The liposomes are made from either hydrogenated soy phosphatidylcholine or PEG-DSPE (abstract, Examples 4 and 7).

Allen (4,920,016) discloses liposomes made from DSPC and having a diameter of 170 nm. The active agents include anti-tumor agents and antibiotics (abstract, columns 10-11, Table 1 in Example 3).

What is lacking in Woodle 633, 556 or Allen 016 is the teaching of indolocarbazole derivatives as the active agent. However, it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Woodle, especially in view of EP which teaches the knowledge in the art of encapsulation of this compound in the liposomes. One of ordinary skill in the art would expect similar encapsulation.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that these primary references are all less relevant than EP

646 since Woodle and Allen all encapsulate insulin and GADF, which do not readily leak from liposomes, in contrast to the indolocarbazole derivative of the pending claims. These arguments are not persuasive since the references teach many other active agents besides insulin and GADF and applicant has not shown that these agents are different from instant active agent in terms of leakage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S Kishore/

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK